

PATENT COOPERATION TREATY

INTERNATIONAL SEARCHING AUTHORITY

PCT

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

<p>Applicant's or agent's file reference see form PCT/ISA/220</p>		<p>Date of mailing (day/month/year) see form PCT/ISA/203</p>	
<p>International application No. PCT/US2009/042494</p>		<p>International filing date (day/month/year) 01.05.2009</p>	
<p>International Patent Classification (IPC) or both national classification and IPC INV. G06F19/00</p>			
<p>Applicant SMITHS MEDICAL MD, INC.</p>			

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

<p>Name and mailing address of the ISA:</p> <p> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465</p>	<p>Date of completion of this opinion</p> <p>see form PCT/ISA/203</p>	<p>Authorized Officer</p> <p>Barba, Michelangelo</p> <p>Telephone No. +49 89 2399-2732</p>
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OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2009/042494

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material:
 on paper
 in electronic form
 - c. time of filing/furnishing:
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

OPINION OF THE
IONAL SEARCHING AUTHORITY

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

the entire international application
 claims Nos. 1-87

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

the description, claims or drawings (*Indicate particular elements below*) or said claims Nos. 1-87 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for the whole application or for said claims Nos. 1-87

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

OPINION OF THE
NATIONAL SEARCHING AUTHORITY

International application No.
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1 The present set of claims is so broad and unclear that the claims as a whole are not in compliance with the provisions of clarity of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.
The reasons are the ones specified herein under in Part VIII of this Written Opinion of the International Searching Authority.
The non-compliance with the substantive provisions is to such an extent that a meaningful search of the whole claimed subject-matter could not be carried out (Article 17(2) PCT and PCT Guidelines 9.30).
 - 1.1 Moreover, because also throughout the originally filed description the same vague and broad wordings have been used, no reasonable basis in the application that clearly indicates the subject-matter which might be expected to form the subject of the claims later in the procedure could have been determined, no search at all was deemed possible.
 - 1.2 The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1 (e) PCT).
The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.
If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17 (2) declaration be overcome.

Re Item VII

Certain defects in the international application

- 2 The features of present independent claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 2.1 The statements of the first paragraph of the description ("Related Patent Applications") clearly stem from a corresponding American application, but are evidently irrelevant to the present international application. They should therefore be deleted Rule 9.1(iv) PCT.
- 2.2 Furthermore, from page 19 line 32 to page 21 line 19, the description contains general statements that the extent of protection may be expanded in some vague and not precisely defined way. Such general statements shall be deleted as contrary to Article 6 PCT, cf. also PCT Preliminary Examination Guidelines, C-III, 4.3a.

Re Item VIII

Certain observations on the international application

- 3 The application does not meet the requirements of Article 6 PCT, the reasons therefor being the following.
 - 3.1 Although claims 1, 12, 23, 34, 44, 50, 56, 59, 62, 71, 79 and 85 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
 - 3.2 Moreover, also when making reference to the present description no passages could be found that might suggest or guide to a possible interpretation or understanding of the extent of the scope of the subject matter intended to be claimed.

3.3 Furthermore, the present set of claims does not meet the requirements of clarity as set out in Article 6 PCT, for the following additional reason.

The present set of claims includes so many dependent claims, and they are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as they erect a smoke screen in front of the skilled reader when assessing the subject matter intended to be claimed, which is against the provisions of Article 6 PCT.

Final Remarks

4 The applicant/representative was informed that the search is the responsibility of the ISA under Chapter I of the PCT, the procedure before the ISA is closed and that there is no provision in the PCT for a review of or an appeal against the findings of the ISA by the IPEA.